Serial No.: 10/736,461

REMARKS

By this Office Action, the Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

- Group I. Claims 1 and 3, drawn to a method for screening and/or diagnosing cancer comprising detecting and/or quantifying in a biological sample a DTD polypeptide identified as SEQ ID NO: 1, classified in class 435, subclass 7.1.
- Group II. Claim 1, drawn to a method for screening and/or diagnosing cancer comprising detecting and/or quantifying in a biological sample a nucleic acid molecule (SEQ ID NO: 2), which encodes SEQ ID NO: 1, classified in class 435, subclass 6.
- Group III. Claims 2, 4, 11, 12, 14-16 and 18, drawn to an antibody and a medicament comprising the antibody, classified in class 530, subclass 387.7.
- Group IV. Claims 5-9, drawn to a method of screening for agents capable of interacting with a polypeptide identified as SEQ ID NO: 1, classified in class 436, subclass 86.
- Group V. Claims 7-9, drawn to a method of screening for agents capable of modulating expression of a nucleic acid molecule identified as SEQ ID NO: 2, classified in class 436, subclass 8.
- Group VI. Claims 10 and 14, drawn to an agent, which alters the expression and/or activity of a DTD polypeptide and a pharmaceutical composition comprising said agent, classified in class 435, subclass 7.4.
- Group VII. Claims 10 and 14, drawn to an agent, which alters the expression of a nucleic acid, classified in class 536, subclass 24.5.
- Group VIII. Claims 11, 14, 15 and 18, drawn to a pharmaceutical composition comprising a nucleic acid, SEQ ID NO: 2, classified in class 514, subclass 44.
- Group IX. Claims 13 and 17, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering a polypeptide identified as SEQ ID NO: 1, classified in class 424, subclass 9.1.
- Group X. Claims 13 and 17, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering a nucleic acid having substantial identity to SEQ ID NO: 2, classified in class 424, subclass 64.

Serial No.: 10/736,461 Attorney Docket No.: 2543-1-034

Group XI. Claims 13 and 17, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering an antibody, classified in class 424, subclass 178.1.

- Group XII. Claims 13 and 17, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering an agent capable of modulating the expression of a polypeptide identified as SEQ ID NO: 1, classified in class 424, subclass 94.1.
- Group XIII. Claims 13 and 17, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering an agent capable of modulating the expression of a nucleic acid molecule identified as SEQ ID NO: 2, classified in class 424, subclass 1.73.

Responsive to the Requirement for restriction, Applicants elect to prosecute the invention of Group XI, with traverse, Claims 13 and 17, which are drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering an antibody, classified in class 424, subclass 178.1.

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of Claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

- 1. Separate classification
- 2. Separate status in the art; or
- 3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner <u>must</u> examine it on the

Serial No.: 10/736,461 Attorney Docket No.: 2543-1-034

merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully submit that the groups designated by the Examiner fail to define compositions and methods, with properties so distinct as to warrant separate Examination and Search. Claims 2, 4, 11, 12, 14-16 and 18 of Group III are drawn to an antibody and a medicament comprising the antibody that are fundamentally related to Claims 13 and 17 of Group XI, drawn to a method for prophylaxis and/or treatment of breast cancer comprising administering an antibody, classified in class 424, subclass 178.1. It is noteworthy in this regard that the antibody of Group III is an antibody that specifically binds to at least one DTD polypeptide of SEQ ID NO: 1. The search for any of the methods separately classified by the Examiner as the invention of Group XI would, therefore, require an additional search of the identical classes wherein the claims of Group III are classified, thus resulting in a duplicate search for the same material. Thus, Applicants submit that the Search and Examination of the entire Application, or, at least, of Group XI with Group III can be made without serious burden, and therefore the Examiner is respectfully requested to reconsider the restriction requirement.

The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that modification to include the Claims drawn to Group XI and Group III of the present invention is in order because these Groups are highly related and, therefore, would not present an undue burden on the Examiner.

No fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

In view of the above, an early action on the merits of the Claims is courteously solicited.

Respectfully submitted,

KLAUBER & JACKSON LLC 411 Hackensack Avenue Hackensack, New Jersey 07601 (201) 487-5800

Date: October 19, 2006

Sarah J. Fashena, Ph.D.
Agent for Applicant(s)

Registration No. 57,600